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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,800	11/06/2000	Thomas Strungmann	4271-29PUS	5697

7590 11/01/2002

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/674,800	Strungmann
Examiner	**Art Unit**
Susan T. Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 12, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *16-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment filed 11/05/01 and 04/10/02, Information Disclosure Statement filed 07/30/01 and 08/12/02, Request for Extension of Time filed 04/10/02, and Amendment C filed 08/12/02.

Information Disclosure Statement

1. The information disclosure statement filed 08/12/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56© most knowledgeable about the content of the information, of each patent listed that is not in the English language. The AF reference has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 26, and 28 are rejected in the use of the phrase "content a first active ingredient", which is recite the broad recitation, but the claim also recites "said first active ingredient comprising at least one of candesartan and one of its pharmaceutically suitable esters or salts" which is the narrower statement of the range/limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). It is unclear if there's more than one candesartan? What is "at least one of candesartan". Further clarification is requested.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 16, 17, and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Frangin et al. US 5,985,915.

Frangin teaches a patch for transdermal composition comprising active ingredients, excipient (column 6, lines 24-65), and at least one additional cardioactive agent selected from the group consisting of diuretic, and angiotensin II, e.g., candesartan (column 8, lines 43-67).

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frangin et al.

Frangin is relied upon for the reasons stated above. In the case that applicant's attorney can over come the above 102(e) rejection, the examiner relies on the 103(a) rejection. Regarding to claims 18-22, the reference differs from the claimed invention by not teaching the specific form of candesartan or its' salts. However, it would have been prima facie obvious for one of the

ordinary skill in this art to, by routine experimentation determine a suitable form of candesartan suitable for transdermal patch.

The examiner notes that Frangin is silent as to the teaching of diuretic or calcium blocker as a second therapeutic agent. However, Frangin teaches the active ingredients selected from benzofuran can be formulated in combination with one or more pharmaceutically vehicles (see abstract). Thus, it would have been obvious for one of the ordinary skill in this art to select more than one cardioactive agent, e.g. diuretic and angiotensin inhibitor, to obtain a transdermal patch containing candesartan.

5. Claims 16, 17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss US 5,616,591, in view of Frangin et al.

Poss teaches a composition for transdermal patch comprising an angiotensin inhibitor agent in combination with a diuretic agent as a second compound (columns 7, lines 40 through column 8, lines 1-29). Poss does not suggest the use of a specific compound of angiotensin inhibitor.

Frangin teaches a transdermal patch composition comprising angiotensin inhibitor agent, e.g., candesartan (column 8, lines 66-67). Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Poss's transdermal patch using candesartan as an angiotensin agent in view of the teaching of Frangin. The reasons for this modification is to obtain a transdermal patch containing candesartan useful for the treatment of heart diseases.

6. Claims 23-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss and Frangin et al., in view of Jalonen et al. US 5,464,628.

Poss and Frangin are relied upon for the reasons stated above. The references are silent as to the teaching of the ingredients of a transdermal patch.

Jalonen teaches a pharmaceutical composition containing substituted imidazole to be administered transdermally (abstract). The transdermal patch comprises a an impermeable backing layer and an adhesive layer; or an impermeable backing layer, an adhesive layer, and a matrix layer; or a drug reservoir system (column 2, lines 36-64). The backing layer can be flexible or non-flexible materials: polyethylene, or polypropylene; the adhesive layer can be polysiloxanes, polyacrylates, or ethylene-vinyl acetate; and the matrix layer can be of natural or synthetic rubbers (column 3, lines 21-51). The composition further comprising carrier and penetration enhancers, e.g., polyethylene glycol, propylene glycol, isopropanol, ethanol, oil, or a mixture thereof (column 2, lines 65 through column 3, lines 1-20). Thus, it would have been prima facie obvious for one of the ordinary skill in this art to prepare Poss's and Frangin's composition in a transdermal patch in view of the teaching of Jalonen. The reasons for this modification is to obtain a candesartan transdermal patch that will provide a high bioavailability of drug penetration.

Response to Arguments

7. Applicant's arguments filed 08/12/02 have been fully considered but they are not persuasive. The examiner maintains the original rejections.

Applicant argues that Frangin does not teach a transdermal therapeutic system containing candesartan or an ester or salt thereof. Contrary to the applicant's argument, Frangin teaches pharmaceutical composition that can be administered through oral, topical or transdermal (column 6, lines 24-28), and candesartan is one of the active agents that can be used (column 8, lines 43-67). Accordingly, such language does suggest transdermal system containing candesartan.

Applicant argues that not every active agent can be administered in the form of a transdermal patch. The examiner is called upon to comply with the requirements of 37 C.F.R. 11.104(d)(2). However, if a prima facie case of obviousness is established, the burden is shifted to the applicant to come forward with evidence to rebut the prima facie case. See, *e.g., Dillon*, 919 F.2d at 692, 16 USPQ2d at 1901. Rebuttal evidence can be presented by way of an affidavit or declaration under 37 CFR 1.132, *e.g., Soni*, 54 F.3d at 750, 34 USPQ2d at 1687; *In re Piasecki*, 745 F.2d 1468, 1474, 223 USPQ 785, 789-90 (Fed. Cir. 1984). Frangin teaches candesartan as one of the active agents used in his pharmaceutical composition, which can be administered orally, parenterally, topically, or transdermally. Absent showing evidence on the contrary, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine

experimentation determine a suitable dosage form to administer candesartan, *e.g.*, by transdermal.

Applicant argues that Poss does not provide any examples of angiotensin II inhibitors, such as candesartan in a transdermal patch. However, Poss is relied upon for the teaching within the four walls patent. Poss cannot be limited to his best mode as describe or not describe in the examples. Further more, Poss is relied upon for the teaching of angiotensin II inhibitor compounds can be administered transdermally (columns 7-8). Thus, it would have been obvious for one of ordinary skill to combine Poss and Frangin to obtain transdermal patch containing candesartan, because candesartan is well known in the pharmaceutical art to be one of the angiotensin II inhibitors.

Applicant argues that Jalonen acknowledges that not all therapeutically active substances are suitable for transdermal administration. Nonetheless, Jalonen does not exclude angiotensin II inhibitors, more particular, candesartan. Jalonen is relied upon for the teaching of the transdermal patch that contains active ingredients. In the instant case, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It would have been obvious for one

of ordinary skill in the art to combine the teaching of Frangin and Jalonen since the references are teaching transdermal patch containing therapeutic agents.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600